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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,708	09/19/2001	Gerald R. Crabtree	STAN201	4284

24353 7590 05/05/2004

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,708

Applicant(s)

CRABTREE ET AL.

Examiner

Sean R McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-11, 15-18 and 30-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-11, 15-18, and 30-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 2/18/04.
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-11, 31, 36-39, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-11 and 37-39 are unclear since claim 8 recites in the last line "said method comprising" while providing nothing in context to be comprised thereing, for example. This suggests that some other step is intended while providing no such step in the claims, for example.

Claims 31, 36, and 41 all recite "rapamaycin". There is no disclosure or teaching of what a "rapamaycin" is. It is assumed that the intention was rapamycin and an amendment to correct such a typographical error would be remedial. In the application of art below it is assumed that it was intended that "rapamaycin" was intended to read "rapamycin".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-11, 15-18, 35, 37-40, and 42-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang et al [Carcinogenesis Vol. 14(1):67-71, 1993].

Jiang et al disclose the inhibition of tumor formation in a mouse comprising the administration of FK506 and also disclose that it was known in the art that administration of cyclosporin A, which is "remarkably similar" in biological properties with FK506, to mice inhibited skin tumor formation in mice. The prior art methods include all the steps of the instant methods and the effects of claims 8-11 are considered to be inherent in the prior art methods.

Applicant's arguments filed 2/18/04 have been fully considered but they are not persuasive. Applicant argues that the amendment to read *in vitro* overcomes the rejection of record for claims 1-4. A new grounds of rejection has been established to address this amendment to the claims. Applicant argues that the amendment to the claims to recite "systemically" administering defines over the prior art. The position is not agreed with. There is no specific definition of systemic delivery in the specification and indeed the cite relied upon for the support of the amendment "systemic", paragraph 25, recites various methods of delivery including transdermal. It is clear that the prior art is not overcome with the amendment.

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Claims 1-4, 30-34, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Flanagan et al [Nature Vol. 352:803-807, 08/29/1991].

Flanagan et al disclose the administration of FK506, rapamycin and cyclosporin A to cells in sufficient quantities to inhibit NF-AT. The prior art discloses each and every step recited in the claims. Any effects not observed in the prior art methods are assumed to be inherent, without evidence to the contrary, since the steps of the instant claims are clearly disclosed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al as applied to claims 8-11, 15-18, 35, 37-40 and 45-47 above, and further in view of Flanagan et al.

The instant claims recite the use of rapamycin and synthetic mimetic thereof and cyclosporin A mimetics and derivatives in the claimed methods. It is clear from the teachings of Jiang et al that it would be obvious to use compounds with common biological properties with FK506 in their methods since it was the common properties of FK506 to cyclosporin A that caused them to determine the effects of FK506, for example (see page 67, for example).

It is further taught in Flanagan et al that FK506 and cyclosporin and FK506 have similar properties as is evidenced by their interchangeable use in the methods taught therein, for example. It is further taught that rapamycin is a structural analogue of FK506 and have taught its use as a control in experiment utilizing FK506, for example.

The prior art therefore clearly teaches the interchangeable use of Cyclosporin A and FK506 based on their biological properties which would clearly indicate to one in the art to use compounds with the specific biological properties of cyclosporin A and FK506 in the method of Jiang et al and furthermore it is clear that one would utilize rapamycin as a control in the methods of Jiang et al, for example, as taught by Flanagan et al.

The invention, as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

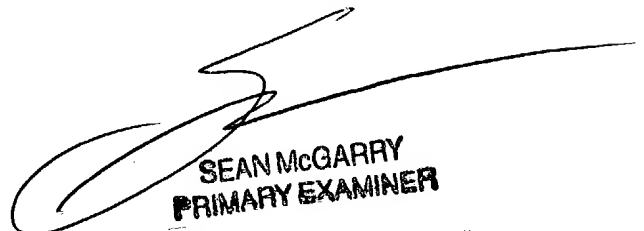
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRM


SEAN MCGARRY
PRIMARY EXAMINER
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